

Exploring Implications of the Nonprescription Drug Safe Use Regulatory Expansion (NSURE) Initiative on Reimbursement and Access

Background on the Nonprescription Safe Use Regulatory Expansion (NSURE) Initiative

Access to medication plays a significant part in the ability of patients and consumers to manage their healthcare and maintain their health. However, many in the United States (U.S.) lack regular access to adequate pharmaceutical care, an issue which contributes to the medical undertreatment of many common diseases and conditions.^{1,2,3} Poor medical adherence may also contribute to this problem, as research suggests 20% to 30% of prescription medications are never filled and 50% of medications for chronic disease are not taken as prescribed.⁴ Improving access to appropriate pharmaceutical care while ensuring the safe and effective use of drugs can contribute to mitigating the problem of undertreatment. Addressing undertreatment requires action by all health care stakeholders, including providers, patients, payers, regulators, and medical product manufacturers.

Recognizing the impact of undertreatment on public health, the U.S. Food and Drug Administration (FDA) is exploring how a regulatory expansion of the nonprescription drug class might increase access to medications for undertreated diseases and conditions. This initiative, known as the *Nonprescription Safe Use Regulatory Expansion (NSURE)*, is exploring one potential strategy for mitigating the public health problem of undertreatment through FDA's existing regulatory authorities. The NSURE initiative is aimed at identifying how, within the existing two-class system of prescription and nonprescription drug classes, Conditions of Safe Use might be developed and implemented as part of a comprehensive approach to drug regulation that ensures that certain drugs will be safe and effective in the nonprescription setting.

The NSURE initiative has the potential to increase access to important medications, and could serve as a new paradigm to bring undertreated patients into the healthcare system. Developing the NSURE initiative will require an understanding of many of the health, economic, behavioral, and technological factors involved. An essential component of this initiative is the investigation and analysis of how health care professionals and innovative technologies can serve as a condition to the safe use of drugs in a nonprescription setting. Through a cooperative agreement with FDA, the Engelberg Center for Health Care Reform at the Brookings Institution convened two expert workshops which explored these issues.

The first expert workshop, held on November 8, 2012, explored issues and practical considerations in the development of the NSURE initiative. Stakeholders investigated strategies and opportunities for health care professionals to utilize their roles in the community setting as Conditions of Safe Use and

¹ Shrunk W, et al. The Quality of Pharmacologic Care for Adults in the United States. *Medical Care* 44(10): 936-56

² Kenney G, et al. A Decade of health Care Access Declines for Adults Holds Implications for Changes in the Affordable Care Act. *Health Affairs* 2012; 31: 5899-908

³ McGlynn, E, et al. The Quality of Health Care Delivered to Adults in the United States. *New England Journal of Medicine* 348(26): 2635-645

⁴ Viswanathan M, et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review. *Annals of Internal Medicine*. 2012 Dec; 157(11):785-795.

discussed lessons from previous initiatives that addressed pharmaceutical access. A summary of the workshop discussion is available on the Brookings event [webpage](#).

The second expert workshop, held on May 9, 2013, investigated the use of technologies as a Condition of Safe Use for medications within a nonprescription setting. This workshop explored stakeholder perspectives on the role of technology to support the safe and effective use of nonprescription products and investigated the integration of innovative technologies, such as mobile applications and in-store kiosks, into the existing health care delivery system. This workshop also explored the use of such technologies in underserved communities and populations where technologies are not widespread. Additional information is available on the Brookings event [webpage](#).

Access and Reimbursement Considerations of the NSURE Initiative

Currently, a wide range of private, federal, and state health insurance programs provide reimbursement for prescription medications; however, coverage programs for nonprescription medications remain infrequent and product-specific. It is important to understand the potential impact of NSURE on costs and access to medications, as potential candidates for NSURE include current prescription products that could be approved as nonprescription with a Condition of Safe Use. Understanding the effects of a switch from prescription to nonprescription on access, including effects on reimbursement and cost, can help to inform the development and implementation of the NSURE initiative.

Background on Nonprescription Medications and “Rx-to-OTC” Switches

Pharmaceutical products in the United States are regulated in a two-class system of prescription (Rx) and nonprescription (i.e., over-the-counter, "OTC") medications. Nonprescription medications are widely available to patients and consumers through retail outlets and pharmacy locations. It is estimated that 240 million people in the U.S. currently use nonprescription medications, which span over 300,000 products and 80 therapeutic classes of drugs.^{5,6}

As part of the nonprescription drug approval process, product manufacturers (i.e., sponsors) must demonstrate that patients and consumers are able to self-diagnose, self-select, and comprehend the labeling to guide actual use of the product. In addition, special consideration regarding potential for abuse is given to nonprescription medications. Over one-hundred active ingredients and dosage forms have been directly introduced into the nonprescription market or transferred from prescription to nonprescription over the last 40 years.⁷

In general, there are two methods by which new or existing medications are able to be classified as nonprescription. First, products can be approved for nonprescription use by conforming to the requirements outlined within FDA's OTC monographs, a defined list of ingredients approved for OTC marketing. Second, products can be approved for nonprescription status through the New Drug Application process. The process of reclassifying drugs from prescription to nonprescription status is commonly referred to as an "Rx-to-OTC" switch. Rx-to-OTC switches have enabled a range of prescription medications to become widely available as nonprescription products, such as second-generation antihistamines, nicotine replacement therapies, and acid reducers.^{8,9} Certain Rx-to-OTC

⁵ U.S. Food and Drug Administration (October 2013). Drug Applications for Over-the-Counter (OTC) Drugs (page).

⁶ Consumer Healthcare Products Association. The Value of OTC Medicine to the United States, January 2012.

⁷ Soller R W, et al. OTC Considerations for Rx-to-OTC Switch. *SelfCare* 2011; 2(5):117-138

⁸ Cohen J, et al. Assessing the economic impact of Rx-to-OTC switches: systematic review and guidelines for future development. *Journal of Medical Economics* 2013; 16(6): 835-44

drugs have retained a “dual status,” and are available simultaneously in prescription and nonprescription forms.

Impact of Rx-to-OTC Switches on Cost and Access

Previous Rx-to-OTC switches can provide valuable insight into the effect of future Rx-to-OTC transitions on cost and access. The public health and economic impact of switching medications from Rx-to-OTC can be influenced by a number of factors, including medication price, coverage, product exclusivity, and industry competition.^{8,9} While the impact of each Rx-to-OTC switch on costs, access, and public health is unique to a given product, a few patterns have been identified.

Rx-to-OTC switches have the potential to provide a number of benefits to patients, payers, and other stakeholders. Research has suggested that certain Rx-to-OTC switches have provided an increase in access and utilization of treatment, leading to a greater public health benefit (e.g., nicotine replacement therapies).^{10,11} Additionally, patients and payers may benefit from economic and cost-saving opportunities. Evidence suggests that the cost of some drugs may decrease following a switch to nonprescription status.^{8,9} Cost savings might result from reducing the number of unnecessary physician visits or medical encounters solely used to obtain prescriptions.⁹ Emergency room visits may also be reduced as a result of increased access to early and appropriate treatment for acute symptoms.⁸ Following the switch of certain prescription medications, a significant decrease has been observed in the number of physician visits, laboratory charges, and prescriptions dispensed for enrollees.^{9,12,13} This has the potential to decrease medical expenditures for patients, payers, and managed care organizations.

However, a number of potential drawbacks have also been associated with medications moving from Rx-to-OTC. Third-party payers often drop coverage and reimbursement for medications following an Rx-to-OTC switch. As a result of loss of coverage, switches generally shift costs to patients and consumers that may result in higher out-of-pocket costs. In instances where out-of-pocket costs are higher than previous prescription copayments, an Rx-to-OTC switch may result in lower utilization rates. A decrease in the utilization of effective, high-value medications has the potential to result in negative health outcomes and increased costs for patients and payers. Others have suggested that the loss of health care professional oversight for products moving from Rx-to-OTC has the potential to increase healthcare costs due to missed self-diagnosis or inappropriate self-medication by a patient.⁹ Concerns have also arisen regarding the availability of medications for patients who do not require treatment, resulting in unnecessary costs due to overuse, and potential delays in correct diagnoses.¹⁴ Others have expressed concerns regarding the widespread use of certain nonprescription products and their potential to mask symptoms of more severe conditions.⁹

⁹ Harrington P and M. Shepherd. Analysis of the Movement of Prescription Drugs to Over-the-Counter Status. *Journal of Managed Care Pharmacy* 2002; 8(6) 499-508

¹⁰ Shiffman S, et al. Public Health Benefit of Over-the-Counter nicotine medications. *Tob Control* 1997; (6) 306-10

¹¹ Stomberg C, et al. *Health* (5) 2013; 1667-1680

¹² Gurwitz JH, et al. The effect of an Rx-to-OTC switch on medication prescribing patterns and utilization of physician services: the case of vaginal antifungal agents. *Health Serv Res*. 1995; 30(5): 672-85

¹³ Lipsky M, et al. Impact of vaginal antifungal products on utilization of healthcare services: evidence from patient visits. *J Am Board Fam Pract*. 1999; 13(3): 178-82

¹⁴ Ferris D, et al. Over-the-counter Antifungal Drug Misuse Associated with Patient-Diagnosed Vulvovaginal Candidiasis. *Obstet Gynecol*. 2002; 99(4): 19-25

Factors to Consider for Coverage and Reimbursement in the NSURE Initiative

While some of the effects of Rx-to-OTC switches can be generalized over a population, the impact on individual patients is variable and dependent on specific drug benefit plans and medication costs. Coverage of nonprescription drugs, including potential drugs that may fit within the NSURE paradigm, will be an important factor that determines the effect of an Rx-to-OTC switch on access and public health.

Numerous state and private insurance providers have offered nonprescription drug coverage for medications that have switched from Rx-to-OTC. For example, an Arkansas state employee health plan has chosen to include coverage of nonprescription omeprazole (e.g., Prilosec), a medication used to treat heartburn, ulcers, and acid reflux disease. Research has demonstrated that coverage for this OTC medication produced cost savings and resulted in small increases in utilization.¹⁵ This program incentivized the purchase and dispensing of OTC medications through copayments, larger quantities of nonprescription medications, and pharmacists' compensation for OTC dispensing.¹⁵

A number of self-insured employer groups have also implemented coverage for a variety of OTC products, including OTC medications for acid reflux disease and allergies.¹⁶ In addition, many states provide supplemental OTC drug coverage through medical assistance programs and Medicaid. Payment for nonprescription medications is also possible through a number of federal programs, including tax-exempt savings accounts such as Flexible Spending Accounts (FSAs), Health Reimbursement Arrangements (HRAs,) and Health Savings Accounts (HSAs). However, recent reforms have mandated that nonprescription medications require physician prescription for reimbursement from health spending accounts.¹⁷ Additionally, a variety of OTC medications are eligible for coverage through Medicare Advantage.¹⁸

Additionally, a variety of tools have been developed and covered by third-party payers to improve medication adherence, safety, and disease management. For example, employee-based insurance programs and Accountable Care Organizations (ACOs) have instituted medications therapy management (MTM) programs for conditions such as diabetes, coronary heart disease, and hypertension.^{19,20} Evidence suggests that these pharmaceutical care services have resulted in improved clinical outcomes for patients and decreased total direct medical costs for patients.²¹ A variety of MTM services are currently eligible for coverage through Medicare Part D. These programs, which are currently geared towards appropriate use of prescription products, may serve as tools to improve adherence and monitor for safety problems for drugs that may fall within the NSURE paradigm, in addition to services that pharmacists and nurse practitioners may provide in the ambulatory settings.

¹⁵ Harris B, et al. Effects on the Cost and Utilization of Proton Pump Inhibitors from Adding Over-the-Counter Omeprazole to Drug Benefit Coverage in a State Employee Health Plan. *Journal of Managed Care Pharmacy*. 2004; 10(5): 449-55

¹⁶ The Savitz Organization. 2012 Survey of Employer-Provided Health Benefits.

¹⁷ U.S. Internal Revenue Service (October 2013). Affordable Care Act: Questions and Answers on Over-the-Counter Drugs (page).

¹⁸ U.S. Centers for Medicare and Medicaid (October 2013). Medicare Managed Care Manual: Chapter 4 Benefits and Beneficiary Protections (page). Rev. 115, 08-23-13

¹⁹ McConnell K, et. al. Coronary Artery Disease and Hypertension: Outcomes of a Pharmacist-Managed Blood Pressure Program. *Pharmacotherapy* 2006; 26(9)

²⁰ Cranor C, et. al. The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program. *Journal of the Pharmaceutical Association*. March/April 2004; 43(2): 173-83

Exploring the Impact of NSURE on Access and Reimbursement

In an effort to support the development of the NSURE initiative, the Engelberg Center of Health Care Reform at Brookings will hold an expert workshop to explore how an expansion of the nonprescription drug class might impact drug access and reimbursement. This workshop will investigate effects of previous prescription-to-nonprescription medication switches, incentives for reimbursement and coverage of nonprescription medications, and potential mechanisms for reimbursement of nonprescription drugs with Conditions of Safe Use.

Session I: Reviewing Effects of Rx-to-OTC Switches on Access

- Historically, what has been the effect of an “Rx-to-OTC” switch on patient access to, and use of a product?
- How have Rx-to-OTC switches affected the cost and reimbursement of a product?
- What are the effects of Rx-to-OTC switches on health care costs and spending?
- How might the lessons from Rx-to-OTC switches inform development of the NSURE paradigm?
- How can experiences and information gathered from prior Rx-to-OTC switches be applied specifically to nonprescription medications with Conditions of Safe Use?

Session II: Identifying Incentives for Reimbursement of Nonprescription Drugs with Conditions of Safe Use

- What are incentives for payers, Accountable Care Organizations (ACOs), managed care organizations, and other stakeholders to provide coverage for nonprescription medications with Conditions of Safe Use?
- Are there competitive advantages for covering these products?
- What are important factors or considerations that may influence coverage decisions for these products?
- How might reimbursement for medications with Conditions of Safe Use be shown to improve outcomes and lower costs for payers?
- What are barriers or challenges that may prevent payers from reimbursing nonprescription medications with conditions of safe use?
- Are there additional evidentiary considerations that need to be fulfilled to support coverage of these products? What evidence of impact on quality, safety, and value is needed to support coverage?

Session III: Exploring Potential Mechanisms for Reimbursement of Nonprescription Drugs with Conditions of Safe Use

- How might coverage be expanded to include reimbursement for nonprescription medications with Conditions of Safe Use?
 - Medicare Part D (e.g., supplemental benefits through enhanced alternative coverage)
 - Medicare Part C (e.g., Medicare Advantage Plans)
 - Prescription Drug Plans (PDP)
 - Medicare Advantage Plans
 - Accountable Care Organizations (ACOs)
 - Managed care groups
 - Flexible Spending Accounts (FSAs), Health Reimbursement Arrangements (HRAs), and Health Savings Accounts (HSAs)
- What might be required of the various stakeholders?
 - Patients?

- Health care professionals?
 - Payers?
- Under this framework, how might nonprescription medications with Conditions of Safe Use be distinguished from nonprescription medications more broadly?
 - How might nonprescription medications with Conditions of Safe Use be distinguished from prescription medications?
- How can policies incentivize patients to use nonprescription medications with Conditions of Safe Use?